UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

WISCONSIN MASONS' HEALTH CARE FUND, Individually And On Behalf Of All Others Similarly Situated, Plaintiff, v. ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., PENWEST PHARMACEUTICALS CO., and IMPAX LABORATORIES INC., Defendants.	Civil Action No. CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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Plaintiff Wisconsin Masons' Health Care Fund ("the Fund") brings this class action, on behalf of itself and all others similarly situated, against Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., and Penwest Pharmaceuticals Co. (collectively "Endo"), and Impax Laboratories, Inc. ("Impax"), (Endo and Impax collectively "Defendants"), based upon personal knowledge as to facts pertaining to itself, the investigation of counsel and upon information and belief as to all other matters, and alleges as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants' overarching anticompetitive scheme to allocate and unreasonably delay competition in the market for extended release oxymorphone hydrochloride,[1] which Endo sells under the brand name Opana ER. Defendants' unlawful scheme included a payment from Endo to Impax of more than $112 million in cash in exchange for Impax's agreement to keep its generic extended release oxymorphone hydrochloride out of the market for two and a half years – from June 2010 to January 2013. Endo used the period of delay that it bought from Impax to switch the market for Opana ER to a new formulation of Opana ER ("Opana ER CRF").[2] But for Defendants' market allocation scheme, Impax would have launched its generic extended release oxymorphone hydrochloride as early as June 14, 2010 for 5, 10, 20, and 40 mg dosage strengths, and July 22, 2010 for the 30 mg dosage strength when the FDA granted Impax final approval for those strengths, and the vast majority of sales of those strengths would have gone to Impax's less expensive generic. As alleged below, Defendants' market allocation scheme injured Plaintiff and the Class of End-Payor purchasers they seek to represent (as defined below), causing them to pay overcharges.

[1] Hydrochloride is also referred to by the acronym "HCL."
[2] CRF is an acronym for "crush resistant formulation."

2. Oxymorphone hydrochloride, an opioid antagonist, has been marketed and sold by Endo in the United States for almost 50 years in various dosage forms, including a rectal suppository and an intravenous drip. Oxymorphone hydrochloride was also available in tablet form during the 1960s and early 1970s. In the 1990s, Endo decided to revive tablet formulations of oxymorphone hydrochloride. However, Endo knew that the longest period of (non-patent) regulatory exclusivity that Endo could obtain for its revived tablet formulation of oxymorphone hydrochloride was three years. The original United States patent on oxymorphone hydrochloride itself was issued in the 1950s and expired long ago.

3. In order to obtain a longer period of exclusivity, Endo Pharmaceuticals, Inc. licensed four time release patents from Penwest Pharmaceuticals Co. ("Penwest") and developed extended release oxymorphone hydrochloride tablets, which Endo named Opana ER. Endo listed the Penwest time release patents in the FDA's Orange Book (discussed below) as covering Opana ER.

4. Endo then embarked on a strategy to block generic competition to Opana ER beyond three years.

5. First, Endo sued generic manufacturers, including Impax, Actavis South Atlantic LLC ("Actavis"), Sandoz, Inc. ("Sandoz"), Barr Laboratories, Inc. ("Barr"), Roxane Laboratories, Inc. ("Roxane"), and Watson Laboratories, Inc. ("Watson") – each of which sought to market generic extended release oxymorphone hydrochloride (i.e., generic Opana ER) – for purportedly infringing the Penwest time release patents. Under the Hatch-Waxman Act (discussed below), the mere filing of these lawsuits prevented the Food and Drug Administration ("FDA") from approving the generic drug applications for each of these generic manufacturers for 30 months, regardless of the merits of the lawsuits.

6. Second, Endo ended its litigation with Impax – the first-filer potential generic competitor for the vast majority of Opana ER sales (the 5, 10, 20, 30, and 40 mg dosages) – by entering into an anticompetitive agreement (the "Exclusion Payment Agreement") whereby Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market for two and a half years in exchange for a large future cash payment and other consideration from Endo. The Exclusion Payment Agreement contained three forms of payment to Impax:

i. A future cash payment from Endo to Impax based on sales of Opana ER in the quarter immediately prior to the delayed Impax launch date established in the Exclusion Payment Agreement (which cash payment in the amount of $102,049,000 was received by Impax in April 2013);

ii. Endo's agreement not to launch an "authorized generic" (basically, brand Opana ER but marketed and priced like a generic, as explained below) during Impax's first 180 days on the market with its generic extended release oxymorphone hydrochloride; and

iii. A cash payment from Endo to Impax of $10 million up front with an obligation to pay an additional $30 million under the guise of a development and co-promotion agreement for Impax's yet-to-be approved product to treat Parkinson's disease.

Thus, in exchange for at least $112 million in cash (and up to $142 million in cash) and other consideration from Endo, Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market until January 2013 – two and a half years after it received final approval from the FDA to sell generic versions of Opana ER.

7. Third, Endo ended its litigation with Actavis, Sandoz, Barr, Roxane, and Watson and used the Exclusion Payment Agreement to create a "bottleneck" whereby no other generic manufacturer could come to market until after Impax had been on the market for 180 days with generic versions of 5, 10, 20, 30, and 40 mg Opana ER tablets.

8. Beginning in 2012, long after the vast majority of brand Opana ER sales would

have switched to the generic, but for Endo's illegal Exclusion Payment Agreement, Endo launched Opana ER CRF and set about converting all Opana ER prescriptions to Opana ER CRF. Thus, when Impax belatedly launched its generic version of Opana ER in January 2013, the market for Opana ER was substantially eroded and, because generic versions of Opana ER are not AB-rated to Opana ER CRF (as discussed below), generic Opana ER cannot be automatically substituted for Opana ER CRF by pharmacists further magnifying the anticompetitive effect of Defendants' unlawful conduct. Apparently anticipating Endo's market switch from Opana ER to Opana ER CRF, Impax had structured the bulk of the cash payment it would receive under the Exclusion Payment Agreement to ensure that the payment was based on sales of Opana ER in the quarter prior to Impax's own launch. The Exclusion Payment Agreement provided that if sales of Opana ER were below a predetermined contractual threshold in the quarter immediately prior to January 1, 2013, Endo would make a cash payment to Impax, which cash payment would be larger the further the Opana ER sales fell below the predetermined contractual threshold. In this way, Impax made sure that it would be paid very well for not competing, even if Endo successfully switched the market from Opana ER to Opana ER CRF (as Endo in fact did) and thereby undercut the generic Opana ER sales that Impax would ultimately obtain.

9. The "basic reason" for the Exclusion Payment Agreement was Defendants' "desire to maintain and to share patent-generated monopoly profits" and therefore the Agreement is "likely" unlawful. *FTC v. Actavis, Inc.*, 570 U.S. ____ , 133 S. Ct. 2223, 2237 (2013). Moreover, the millions of dollars Endo paid to Impax as part of the Exclusion Payment Agreement "provide a workable surrogate for [the] patent[s'] weakness[es]." *Id.* at 2236-37. "An unexplained reverse payment," like the payment at issue here, "itself would normally

suggest that the patentee has serious doubts about the patent's survival." *Id.* at 2236.

10. Endo essentially bribed Impax to stay out of the market for two and a half years to protect Endo's stream of monopoly profits. But for Endo's unlawful and large reverse payment,[3] Impax would have launched its generic earlier than it finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Endo to Impax. Endo literally bought itself freedom from generic competition. Endo and Impax – competitors – conspired to allocate the market for Opana ER and its generic equivalents in a manner that gave each company more exclusivity than it was entitled to in order to maximize profits at the expense of purchasers of Opana ER.

11. But for the Exclusion Payment Agreement, generic versions of 5, 10, 20, and 40 mg Opana ER would have been available as early as June 14, 2010, when the FDA granted final approval for those dosage strengths of Impax's generic Opana ER and a generic version of 30 mg Opana ER would have been available as early as July 22, 2010, when Impax received final approval for that strength. Plaintiff and members of the Class would have substituted the less expensive generic versions for their purchases of brand Opana ER long before Impax belatedly launched its generic in January 2013.

12. Defendants' Exclusion Payment Agreement was designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic versions of Opana ER; (b) fix, raise, maintain or stabilize the price of Opana ER and AB-rated generic versions of Opana ER; and (c) allocate nearly 100% of the U.S. market for Opana ER and its AB-rated generic equivalents to Endo for

[3] In normal patent infringement litigation settlements, the alleged infringer would pay the patent holder. Here, the patent holder (Endo) is paying the alleged infringer (Impax), which is the reverse of what normally occurs (a "reverse payment").

at least two and one half years.

13. Plaintiff brings this action as a class action on behalf of all consumers and third-party payors (collectively, "End-Payors") in certain states, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for brand and/or generic Opana ER, other than for re-sale since June 14, 2010 (see Class Definition below).

14. Plaintiff asserts claims for compensatory and/or treble damages for violations of the State laws enumerated below.

II. PARTIES

15. Plaintiff Wisconsin Masons' Health Care Fund ("the Fund") is a self-funded, multi-employer health and welfare plan governed by the Employee Retirement Income Security Act of 1974 (ERISA), as amended. The Fund is administered by Benefit Plan Administration of Wisconsin, whose offices are at 2901 W. Beltline Highway, Suite 100, Madison, WI 53713-4226. The Fund indirectly purchased, paid and/or provided reimbursement for brand Opana ER other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of Opana ER other than for re-sale once they became available, at supracompetitive prices during the Class Period, and was thereby injured.

16. Defendant Endo Health Solutions Inc. is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Until May 2012, Endo Health Solutions Inc. was known as Endo Pharmaceuticals Holdings Inc.

17. Defendant Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. Endo Pharmaceuticals Inc. is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

18. Defendant Penwest Pharmaceuticals Co. ("Penwest") was acquired by Endo

Pharmaceuticals Holdings Inc. on November 4, 2010. Prior to November 4, 2010, Penwest was a Washington corporation and Endo Pharmaceuticals Inc. and Penwest developed and marketed Opana ER together. Penwest was previously known as Edward Mendell Co.

19. Defendants Endo Health Solutions Inc., Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. are referred to collectively as "Endo."

20. Defendant Impax Laboratories Inc. ("Impax") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

21. Endo and Impax are referred to collectively as "Defendants."

22. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds $5,000,000, and at least one member of the putative class is a citizen of a state different from that of one of Defendants.

24. Venue is appropriate in this district under 28 U.S.C. §1391(b) and (c) because Defendants transact business within this district, and the interstate trade and commerce described herein is carried out, in substantial part, in this District.

25. Defendants' conduct, as described in this complaint, was within the flow of, was

intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

26. During the Class Period, Endo manufactured, sold and shipped Opana ER in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

27. During the Class Period each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their conspiracy.

28. This Court has personal jurisdiction over each Defendant, because each Defendant – throughout the United States and including in this District – has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval and Substitution of Generic Drugs

29. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

30. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the

expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

31. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

32. When a brand manufacturer wishes to make changes to a drug that already has an approved NDA, the brand manufacturer must submit a supplemental new drug application ("sNDA") to the FDA. A sNDA is required to be submitted when a brand manufacturer wishes to change a drug label, market a new dosage strength, or change the way it manufactures a drug.

1. The Hatch-Waxman Amendments

33. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB"

rating.

34. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

35. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

36. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013 total prescription drug revenue had soared to more than $329.2 billion, with generic drugs accounting for 84% of prescriptions.[4] Generic drugs are now dispensed 95% of the time when a generic form is available.[5]

[4] *See Medicine Use and Shifting Costs of Healthcare*, IMS INSTITUTE FOR HEALTHCARE INFORMATICS, at 30, 51 (Apr. 2014), http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last visited June 10, 2014).

[5] *Id.* at 51.

2. ANDA Paragraph IV certification

37. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

38. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30 month stay.

3. First-filer's 180 day exclusivity period

39. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) the brand's authorized generic.

40. As an incentive to generic drug manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA containing a Paragraph IV certification ("first-filer") a 180 day period to market the generic version of the drug, during which time the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been forfeited. The 180 day window is referred to as the first-filer's six month or 180 day "exclusivity," though it is a bit of a misnomer, because a brand drug manufacturer can launch an authorized generic ("AG") version of its own brand drug, under its own NDA, at any time, and brand companies frequently do so in response to generic entry in order to recoup some of the sales they would otherwise lose.

41. The Supreme Court has recognized that "this 180 day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer.[6]

42. A first-filer that informs FDA that it intends to wait until all Orange Book listed patents expire before marketing its generic does not get a 180 day exclusivity period. Congress created this 180 day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

[6] *FTC v. Actavis*, 133 S. Ct. at 2229 (citation omitted).

43. Although later generic ANDA filers must wait 180 days after the first-filer's market entry to get final FDA approval, a brand's AG may enter at any time including during the 180 day exclusivity period.

B. The Competitive Effects of AB-Rated Generic Competition

44. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding branded drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 10% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

45. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic whereby the launch of AB-rated generics results both in a rapid price decline and a rapid sales and purchase shift from brand to generic. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the

market) prices had dropped 85%.[7] As a result, competition from generic drugs is viewed by brand name drug companies, such as Endo, as a grave threat to their bottom lines.

46. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

47. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Endo, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes (as here) resorting to illegal means.

1. The first AB-rated generic is priced below the brand

48. Experience and economic research show that the first generic manufacturer to launch prices its product below the prices of its branded counterpart.[8] Every state either requires or permits that a prescription written for the branded drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand form of the drug. At the same time, there is a reduction in average price paid for a prescription for the drug at issue (brand and AB-rated generic combined).

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[7] *See* FTC STAFF STUDY, P*ay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 8 (Jan. 2010) ("FTC Pay-for-Delay Study"), http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last visited June 10, 2014).

[8] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at ii-iii, vi, 34 (Aug. 2011) ("FTC 2011 AG Study"), http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last accessed June 10, 2014); FTC Pay-for-Delay Study, at 1.

49. During the 180 day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market (as noted above, the brand's AG can be, and often is, on the market during the 180 day exclusivity period). As recognized by the Supreme Court, it is often the case that most of a first-filer's profits are earned during the 180 day exclusivity period.[9]

50. If there is no AG on the market during the 180 day exclusivity, then the first-file prices its product below the brand product, but not as low as if it were facing competition from other generics, including an AG. Since in these circumstances, the first-filer's product competes only with the brand product, and because the brand company typically does not drop the brand product price to match the first-filer, the first-filer does not face the kind of price competition it will when additional generic products, including an AG, are available. Thus, a first-filer earns substantially greater sales and profits without an AG being marketed alongside it during the 180 day exclusivity period.

2. Later generics drive prices down further

51. Once multiple generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[10]

52. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of around 10%, but that with two generic entrants

[9] *See Actavis*, 133 S. Ct. at 2229.

[10] *See, e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act* (Univ. of Miami, Dep't of Economics, Working Paper, Feb. 14, 2004); R. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED., 1993-96 & n.20 (Nov. 2007).

near term retail price reduction is about 50%.

53. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months.[11] In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their brand counterparts, they are typically sold at substantial discounts from the brand price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[12]

3. AGs compete on price, like other generics

54. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand drug, but is sold as a generic product typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. An AG is essentially the same as the brand drug but in a different package. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[13] Brand manufacturers sometimes begin selling AGs before the first-filer generic launches, in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer

[11] FTC 2011 AG Study, at 66-67.
[12] FDA, *Generic Drugs: Questions and Answers*, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last visited June 10, 2014).
[13] K. A. Hassett & R. J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, SONECON, at 3 (May 2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf (last visited June 10, 2014).

generic.

55. Competition from an AG substantially reduces drug prices and the revenue of the first-filer generic (especially during the 180 day exclusivity period when no other ANDA generic can be on the market).

56. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[14] In a report by the FTC issued at the request of Congress in 2011, the FTC found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average.[15] The first-filer generic's revenues decrease when it faces competition from an AG because (a) the AG takes a large share of unit sales away from the first- filer and (b) the presence of the additional generic in the market causes prices, particularly generic prices, to decrease. Thus, if a brand manufacturer agrees to refrain from launching its AG, it can double the first-filer's revenue during the 180 day "exclusivity" period.

57. While a brand manufacturer's agreement not to launch an AG has tremendous financial value to a first-filer generic manufacturer, such an agreement, when used to induce the first-filer to delay its own launch, injures drug purchasers twice over: first, purchasers are forced to pay the high brand prices for longer than they otherwise would; and second, purchasers pay more for the generic in the absence of an AG. FDA analysis reflects that the presence of a second generic causes significant price reductions.[16] Drug purchasers (including the proposed

[14] E. R. Berndt, A. Mortimer, A. Bhattacharjya, A. Parece & E. Tuttle, *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS, 26, no. 3 796 & n.3 (2007), http://content.healthaffairs.org/content/26/3/790.full.html (last visited June 10, 2014).
[15] FTC 2011 AG Study, at 139.
[16] FDA, *Generic Competition and Drug Prices*,

Class of End-Payor purchasers) benefit from the lower prices caused by AG entry and are injured by the higher prices resulting from no AG competition.

58. Freedom from an AG is exceedingly valuable to the first-filer because it hands over all generic sales at higher, supracompetitive prices. Consequently, some brand companies – such as Endo – wield the right to launch an AG as a powerful tool to induce the first-filer generic – such as Impax – to delay its entry. The promise of payment to the first-filer generic in the form of an agreement not to launch an AG is economically equivalent to the promise of a cash payment by the brand manufacturer to the generic because refraining from launching an AG under the agreement effectively doubles the revenues and profits of that generic company from its generic and the brand manufacturer forgoes the sales and revenues it otherwise would have made with its AG. It is as if the brand launched the AG, then handed over its revenues to the first-filer.

59. For a first filer, like Impax, seeking to sell a generic version of a brand product that sold hundreds of millions of dollars annually, like Opana ER, the difference between selling its generic alone, without having to compete against an AG, versus selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. "No AG" agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

60. An anticompetitive agreement entered into between the brand and first-filer generic often subjects later ANDA filers to the delayed entry date agreed to between the brand

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http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm (last visited June 10, 2014).

manufacturer and its conspiring first-filer generic.

61. Later ANDA filers have more modest financial expectations because they have no expectation of market exclusivity. By the time they enter the market there is at least the brand and one other generic on the market (and often, a second generic, in the form of an authorized generic) and thus, the drug has already been commoditized.

62. In the absence of an anticompetitive agreement between the branded company and the first-filer, the later ANDA filers have pro-competitive incentives. They are motivated to fight patents, enter as early as possible, and expend money to challenge the brand company's patent (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as soon as possible.

63. When an anticompetitive agreement with the first-filer is already in place, however, litigation becomes less attractive to later filers. The later generic manufacturers know that the first-filer is not leading the charge against the brand's patent (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive, reverse payment settlement). The later generics have to bear the brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, expect to face competition from at least the first-filer generic, and typically an authorized generic as well. The first settlement between a brand and first-filer generic (such as the Exclusion Payment Agreement at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first-filer, the first-filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

64. Thus, some later generics decide to simply give in to, or join, the conspiracy between the brand company and the first-filer generic and decide to drop their challenges to the

brand's patents and to stay off the market until after entry by the first-filer generic promised to stay off the market until after entry by the first-filer.

65. Exclusion payment agreements are fundamentally anticompetitive and are inconsistent with the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brands instead.

66. Here, Endo and Impax's illegal Exclusion Payment Agreement resulted in at least two years and six months of unlawful monopolization in the market for Opana ER and its AB-rated generic equivalents. Endo delayed generic entry by buying off Impax, the first-filer generic. Endo's settlements with subsequent generic manufacturers (Actavis, Sandoz, Barr, Roxane, and Watson) kept them from entering the market until Impax – the first-filer – did so.

V. STATEMENT OF FACTS

A. Endo Revives Tablet Formulations of Oxymorphone Hydrochloride and Acquires Time Release Patents from Penwest

67. Oxymorphone hydrochloride is a strong opiate antagonist indicated to treat pain and also as a preoperative medication to alleviate apprehension, maintain anesthesia, and as an obstetric analgesic. Oxymorphone hydrochloride was first synthesized in 1914.

68. Endo has marketed and sold oxymorphone hydrochloride in the United States for almost 50 years. On April 2, 1959, the FDA approved Endo's NDA for an injectable form of oxymorphone hydrochloride. On May 31, 1960, the FDA approved Endo's NDA for a rectal suppository form of oxymorphone hydrochloride. Endo marketed the rectal suppository under the brand name Numorphan. In the 1960s, oxymorphone hydrochloride was also made available in an oral immediate release tablet, but was withdrawn from the market in 1972. Endo continued to market Numorphan in injectable and rectal suppository formulations, but these modalities

were used relatively infrequently.

69. In the 1990s, Endo decided to seek FDA approval to re-launch a tablet form of oxymorphone hydrochloride. Endo was aware that because oxymorphone hydrochloride was a previously approved molecule, it would not be eligible for the five years of regulatory exclusivity awarded to approval of "New Molecules." Instead, at most, Endo could be eligible for three years of regulatory exclusivity if Endo submitted new clinical studies in support of its NDA.

70. Not satisfied with the prospect of having just three years of regulatory exclusivity, Endo Pharmaceuticals Inc. purchased from Penwest the rights to patents that it could use to block generic entry beyond those three years. As such, on September 17, 1997, Endo Pharmaceuticals Inc. entered into a collaboration agreement with Penwest to exclusively co-develop opioid analgesic products using Penwest's patents. Penwest possessed several patents related to time release formulations for drug tablets (not to be confused with patents on the drug molecules themselves, known as "compound patents"). In the 1990s, Penwest (then known as Edward Mendell Co.) obtained four patents all related to time release formulations: United States Patent No. 5,128,143 entitled sustained release excipient and tablet formulation (the "'143 patent"), United States Patent No. 5,958,456 entitled controlled release formulation (albuterol) (the "'456 patent"), and United States Patent No. 5,662,933 entitled controlled release formulation (albuterol) (the "'933 patent"). In 2002, Penwest also filed the application for what ultimately issued as United States Patent No. 7,276,250 patent entitled sustained release formulations of oxymorphone hydrochloride (the "'250 patent"). The '143, '456, '933, and '250 patents are collectively referred to as the "Penwest time release patents."

71. Penwest licensed the Penwest time release patents to Endo Pharmaceuticals Inc.

72. Opana ER is an extended release (hence "ER") form of oxymorphone hydrochloride indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

73. Opana IR is an immediate release (hence "IR") form of oxymorphone hydrochloride indicated for the relief of moderate to severe acute pain.

74. Endo began selling Opana ER and Opana IR on or about July 21, 2006. Opana ER was originally approved and marketed in 5, 10, 20, and 40 mg tablets and Opana IR was approved and marketed in 5 and 10 mg tablets.

75. In March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5, 15, and 30 mg. Endo began selling those strengths of Opana ER on April 1, 2008.

76. Based upon Endo's having conducted new clinical studies, Endo was awarded three years of regulatory Endo exclusivity (preventing the FDA from approving any generic versions for three years) for all strengths of Opana ER and all strengths of Opana IR through June 22, 2009, after which Endo's Opana ER and Opana IR monopolies would be subject to generic competition.

77. The lower dosage strengths of Opana ER (5, 7.5, 10, and 15 mg) are typically used to taper patients on and off of Opana ER, whereas the higher dosage strengths of Opana ER (20, 30, and 40 mg) are typically used for the treatment of pain and account for the great majority of Opana ER sales. For example, for the period from January 2009 to March 2011, total sales of Opana ER were just over $757 million, but sales of the 7.5 and 15 mg strengths were only $37.8 million or 5% of total sales (whereas sales of the 20, 30, and 40 mg strengths were $642.8 million, representing 85% of total sales).

1. Opana IR's new clinical study exclusivity expires and generic competition instantly enters the market for Opana IR

78. Although Opana ER and Opana IR[17]17 share the same active ingredients, Endo did not have any patents available to assert in order to extend its Opana IR monopoly beyond the three year new clinical study exclusivity. Thus, Opana IR's exclusivity expired on June 22, 2009 and the normal process of generic entry (including Endo launching an AG) occurred.

79. Following the expiration of Opana IR's exclusivity, generics soon entered the market and drove the price of immediate release oxymorphone hydrochloride down to competitive levels.

80. Roxane was the first to file an ANDA for Opana IR 5 and 10 mg tablets. Roxane's ANDA was approved on September 27, 2010, and Roxane began selling generic immediate release oxymorphone hydrochloride 5 and 10 mg tablets on or about that day.

81. On or around November 1, 2010, Endo launched an AG form of 5 and 10 mg Opana IR tablets.

82. Teva was the second generic company to file an ANDA for 5 and 10 mg Opana IR tablets. The FDA approved Teva's ANDA on February 15, 2011, and Teva began selling generic immediate release oxymorphone hydrochloride 5 and 10 mg tablets soon thereafter. Avanthi, Inc. ("Avanthi") was the third generic company to file an ANDA for 5 and 10 mg Opana IR tablets. Avanthi's ANDA was approved on January 30, 2013, and Avanthi launched thereafter through Avanthi's United States agent KVK-Tech, Inc.

83. But for the anticompetitive and illegal Exclusion Payment Agreement alleged herein, generic competition would have similarly begun for Opana ER in June 2010 and driven the price for extended release oxymorphone hydrochloride down to competitive levels.

[17] However, Opana ER and Opana IR are not AB-rated to each other.

2. Endo leverages Penwest's time release patents to extend Endo's monopoly on Opana ER

84. As noted above, Penwest licensed the '143, '456, '933, and '250 patents to Endo Pharmaceuticals Inc. At the time of launch in 2006, however, Endo listed only the '143 patent in the Orange Book as covering Opana ER. The '143 patent was set to expire in 2008 before the expiration of Endo's three year clinical study exclusivity on June 22, 2009, and thus offered no relevant protection from generic competition.

85. The '456 and '933 patents were not listed in the Orange Book within 30 days of the FDA approving Endo's NDA for Opana ER as required under 21 C.F.R. § 314.53.

86. Pursuant to 21 C.F.R. § 314.53 brand companies must declare all patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product" for listing in the Orange Book within 30 days of filing an NDA. Late listing is listing a patent in the Orange Book more than 30 days after an NDA is approved, and violates 21 C.F.R. § 314.53.

87. Aware that generics would soon submit ANDAs that could be approved in time to allow for the sale of generic Opana ER as soon as Endo's three year clinical study exclusivity expired on June 22, 2009 – as was the case with Opana IR – in October 2007, over a year after Opana ER was launched, Endo late listed three additional Penwest patents – the '250, '456, and '933 patents – in the Orange Book.

3. Endo and Penwest sue Impax, triggering a 30 month Hatch-Waxman Stay

88. As Endo expected, on or about June 29, 2007, Impax filed ANDA 79-087 for its generic extended release oxymorphone hydrochloride. Although the FDA initially accepted Impax's June 29, 2007 ANDA for substantive review, it later rescinded that acceptance due to certain deficiencies.

89. In or before November 2007, Impax resubmitted ANDA 79-087 to the FDA (rectifying the previous deficiencies) and included a Paragraph IV certification stating that Impax's proposed generic extended release oxymorphone hydrochloride tablets in 5, 10, 20, and 40 mg strengths did not infringe the '250, '456, or '933 patents.

90. On December 12, 2007, the FDA advised Impax that its ANDA 79-087 "has been deemed acceptable for filing and substantive review by FDA as of November 23, 2007."

91. On December 13, 2007, Impax sent Endo a notice stating that it had submitted ANDA 79-807 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the '250, '456, and '933 patents. The December 13, 2007 notice also advised Endo that Impax's ANDA 79-087 included a Paragraph IV certification that the proposed manufacture, importation, use or sale of the generic extended release oxymorphone hydrochloride tablets described in Impax's ANDA 79-087 would not infringe any claim of the '250, '456, or '933 patents.

92. On January 25, 2008, Endo sued Impax in the United States District Court for the District of Delaware for infringement of the '456 and '933 patents — but not for the '250 patent. Merely by filing this suit (and regardless of its merit or lack thereof), Endo triggered the automatic 30 month Hatch-Waxman stay, through mid-June 2010, during which time the FDA could not approve Impax's ANDA 79-087 for 5, 10, 20, and 40 mg generic Opana ER.

93. Impax was the first generic company to file an ANDA with a Paragraph IV certification as against the '250, '456, and '933 patents for the 5, 10, 20, and 40 mg strengths of Opana ER. This meant that Impax, as first-filer, was entitled to 180 days of exclusivity for those strengths as against other ANDA filers. As such, by delaying Impax's entry into the market, Endo could delay all generics from entering the market for the 5, 10, 20, and 40 mg strengths of

Opana ER.

94. With the Impax patent litigation pending, in March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5, 15, and 30 mg. Endo launched those strengths of Opana ER on April 1, 2008.

95. Soon thereafter, on June 13, 2008, Impax sent Endo a notice stating that Impax had filed an amendment to ANDA 79-087 to include the 7.5, 15, and 30 mg strengths. The June 13, 2008 notice also advised Endo that Impax's amended ANDA included a Paragraph IV certification that the proposed manufacture, importation, use or sale of the generic extended release oxymorphone hydrochloride described in its ANDA would not infringe any claim of the '250, '456, or '933 patents.

96. Impax was the first Paragraph IV filer against the '250, '456, and '933 patents for the 30 mg strength of Opana ER. As a result, Impax was entitled to 180 days of marketing exclusivity for the 30 mg strength of generic Opana ER (as discussed below, Actavis was the first filer for the 7.5 and 15 mg strengths of generic Opana ER).

97. On July 25, 2008, Endo filed another lawsuit against Impax in the United States District Court for the District of Delaware alleging that Impax's amendment to its ANDA covering the 7.5, 15, and 30 mg tablets of generic Opana ER infringed the '456 and '933 patents (but not the '250 patent).

98. In February 2009, the lawsuits that Endo filed against Impax relating to Opana ER were consolidated and transferred to the United States District Court for the District of New Jersey under the lead docket number 09-831 (the "Impax Patent Litigation").

4. Endo sues other generic manufacturers who submit ANDAs for Opana ER

99. Endo sued subsequent generic ANDA filers for extended release oxymorphone hydrochloride.

a. Actavis

100. In February 2008, Endo received a notice from Actavis stating that Actavis had submitted ANDA 79-046 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the ’250, ’456, and ’933 patents. The Actavis notice advised Endo that Actavis’s ANDA 79-046 included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release hydrochloride tablets described in Actavis’s ANDA would not infringe any claim of the ’250, ’456, or ’933 patents and that the claims in those patents are invalid.

101. On March 28, 2008, Endo sued Actavis in the United States District Court for the District of New Jersey alleging infringement of only the ’456 patent (it did not sue for the ’250 or ’933 patents). By filing this suit, Endo triggered the automatic 30 month stay during which the FDA could not approve Actavis’ ANDA for 5, 10, 20, and 40 mg generic Opana ER until August 2010 at the earliest.

102. On or around May 29, 2008 (covering 7.5 and 15 mg Opana ER) and June 30, 2008 (covering 30 mg Opana ER), Actavis sent Paragraph IV notices to Endo informing it that Actavis had amended its ANDA to include the new dosage strengths of Opana ER and that the Actavis generic Opana ER would not infringe the ’250, ’456, or ’933 patents and that the claims in those patents are invalid.

103. Actavis was the first generic company to file a Paragraph IV certification with respect to the patents that Endo listed for the 7.5 and 15 mg strengths of Opana ER and therefore

Actavis was entitled to the 180 days of market exclusivity upon final FDA approval against other ANDA filers (as discussed above, Impax was the first filer for all other dosage strengths). The 7.5 and 15 mg strengths, however, are used primarily to taper patients on and off of extended release oxymorphone hydrochloride and constitute a very small part of all Opana ER sales.

104. On July 11, 2008, Endo filed a second suit against Actavis in the United States District Court for the District of New Jersey alleging infringement of the ’456 patent only (not the ’250 or ’933 patents) triggering the 30 month Hatch-Waxman automatic stay with regard to the 7.5, 15, and 30 mg strengths of Actavis’s generic Opana ER.

105. The Actavis suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 08-1563 (the “Actavis Patent Litigation”).

b. Sandoz

106. On or about July 9, 2008, Sandoz sent a Paragraph IV notice to Endo with regard to generic Sandoz’s ANDA 90-565 covering generic Opana ER in 5, 10, 20, and 40 mg dosage strengths explaining that the Sandoz generic would not infringe the ’250, ’456, or ’933 patents.

107. On August 22, 2008, Endo sued Sandoz in the United States District Court for the District of Delaware alleging infringement of the ’456 patent only (but not the ’250 or ’933 patents), triggering the 30 month Hatch-Waxman stay.

108. On or about November 17, 2008, by way of Paragraph IV notice and again explaining Sandoz’s view that its generic Opana ER does not infringe the ’250, ’456, or ’933 patents, Sandoz informed Endo that it had amended its ANDA to include 7.5, 15 and 30 mg strengths of generic Opana ER.

109. On or about December 30, 2008, Endo filed a second suit against Sandoz in the United States District Court for the District of Delaware alleging infringement of the ’456 patent

(but not the ’250 or ’933 patents) for 7.5, 15 and 30 mg strengths of generic Opana ER, again triggering the 30 month Hatch-Waxman stay.

110. The two Sandoz suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-836 (the “Sandoz Patent Litigation”).

c. Barr

111. On or about September 11, 2008 (40 mg tablets) and September 12, 2008 (5, 10, and 20 mg tablets), Barr sent Endo Paragraph IV notices with respect to Barr’s generic Opana ER ANDA 90-106 asserting that Barr’s generic products would not infringe the ’250, ’456, or ’933 patents or the patents were invalid or not enforceable.

112. On October 20, 2008, Endo sued Barr in the United States District Court for the District of Delaware alleging that Barr’s ANDA product would infringe the ’456 and ’933 patents (but not the ’250 patent), triggering the 30 month Hatch-Waxman stay.

113. On or about June 1, 2009, Endo received another Paragraph IV notice from Barr covering the 7.5, 15, and 30 mg strengths of generic Opana ER.

114. Soon thereafter, on July 2, 2009, Endo filed another suit against Barr in the United States District Court for the District of New Jersey alleging infringement of only the ’456 and ’933 patents (but not the ’250 patent), again triggering the 30 month Hatch-Waxman stay for the 7.5, 15, and 30 mg strengths of Barr’s generic Opana ER.

115. The two Barr suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-838 (the “Barr Patent Litigation”).

d. Roxane

116. On or about December 28, 2009, Roxane sent Endo a Paragraph IV notice with

respect to Roxane's ANDA 20-0822 for generic Opana ER in a 40 mg dosage strength, explaining that the Roxane generic would not infringe the '250, '456, or '933 patents.

117. On or about January 29, 2010, Endo filed a lawsuit against Roxane in the United States District Court for the District of New Jersey alleging infringement of only the '456 patent (but not '933 or '250 patents), triggering the 30 month Hatch-Waxman stay.

118. On or about March 18, 2010, Roxanne sent a second Paragraph IV notice to Endo (covering generic Opana ER in the 7.5, 10, 15, 20, and 30 mg strengths) and again asserting that the Roxane generic product would not infringe the '250, '456, or '933 patents.

119. On or about April 16, 2010, Endo again sued Roxanne, alleging infringement of the '456 patent (but not '933 or '250 patents), triggering the 30 month Hatch-Waxman stay.

120. The Roxane suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 10-534 (the "Roxane Patent Litigation").

e. Watson

121. On or about January 19, 2010, Endo received a Paragraph IV notice from Watson advising that Watson's ANDA 20-0792 for generic Opana ER in a 40 mg dosage strength would not infringe the '250, '456, or '933 patents.

122. On or about March 4, 2010, Endo sued Watson in the United States District Court for the District of New Jersey alleging infringement of the '456 and '933 patents (but not the '250 patent), triggering the 30 month Hatch-Waxman stay.

123. On or about March 18, 2010, Watson sent a Paragraph IV notice regarding its ANDA for generic Opana ER in 5, 7.5, 10, 15, 20, and 30 mg dosage strengths.

124. On April 23, 2010, Endo amended the Watson complaint to include infringement

allegations regarding the additional dosage strengths and therefore triggered the 30 month Hatch-Waxman stay with regard to the 5, 7.5, 10, 15, 20, and 30 mg strengths as well.

125. The Watson litigation continued in the United States District Court for the District of New Jersey (the "Watson Patent Litigation").

B. Endo and Impax Enter the Exclusion Payment Agreement

1. Endo and Impax enter the Exclusion Payment Agreement during the Impax patent litigation and after FDA's tentative approval of Impax's ANDA

126. From 2007 to 2010, during the 30 month stay period, Endo and Impax litigated their patent infringement suit in the United States District Court for the District of Delaware and then, following transfer and consolidation of the Impax patent cases, in the United States District Court for the District of New Jersey. The Impax Patent Litigation was consolidated for pretrial purposes with the Sandoz Patent Litigation and the Barr Patent Litigation.

127. The case proceeded through discovery and claim construction briefing. Judge Katherine S. Hayden of the District of New Jersey conducted a *Markman* hearing on December 21, 2009 and March 19, 2010. Judge Hayden then entered an order on claim construction on March 30, 2010.

128. In the March 8, 2010 Final Pretrial Order, Impax asserted that it would prove that the '456 and '933 patents were invalid because they were: (1) anticipated by prior art; (2) obvious; (3) and constituted obvious-type double patenting. Further, Impax intended to prove that the '933 patent lacked an adequate written description. Finally, Impax contended that its generic Opana ER did not infringe the '250, '456, and '933 patents (even if those patents were valid).

129. As noted above, the 30 month stay on Impax's ANDA was set to expire (and did expire) on or around June 14, 2010.

130. On May 4, 2010, Impax held its first quarter 2010 earnings call. During that call, Impax's then-President and CEO indicated that Impax was expecting to receive tentative approval of its generic Opana ER ANDA 79-046 by May 23, 2010, and that Impax was preparing to launch generic Opana ER.

131. On May 13, 2010, the FDA tentatively approved Impax's ANDA for all dosage strengths of Opana ER; final approval of Impax's generic Opana ER had to wait for the running of the 30 month Hatch-Waxman stay on June 14, 2010.

132. The next day, May 14, 2010, during a telephonic hearing to discuss Endo's desire to file a preliminary injunction motion to extend the statutory stay of FDA approval of Impax's proposed generic tablets, counsel for Endo represented that Endo had "indications" that Impax was "actually going down that road" of making and stockpiling generic Opana ER product (i.e. Endo understood that Impax was preparing to launch at risk). In response, counsel for Impax represented that Impax "certainly . . . will have the right to launch the [Opana ER generic] product upon final approval in mid-June." Counsel for Impax further represented that, "I certainly today could not say that we would agree not to launch on June 14th. It is our statutory right to launch the product after final approval."

133. With the trial of the Impax and Sandoz Patent Litigations set to commence on June 3, 2010 and conclude by June 17, 2010 (only three days after the thirty month stay was to end and Impax could receive final approval), and to avoid distractions caused by briefing the preliminary injunction motion seeking to extend the statutory stay of FDA approval of Impax's proposed generic tablets filed by Endo, Impax agreed "not [to] launch its ANDA product (generic oxymorphone hydrochloride extended-release tablets) through and including the last trial day as presently scheduled" in a May 20, 2010 letter to Judge Hayden.

134. The bench trial commenced on June 3, 2010, and continued through two days – June 3 and June 7, 2010.

135. Endo was aware that its patents and its patent infringement claims against Impax were weak and that they would not be able to obtain an injunction to stop Impax from launching its generic versions of Opana ER after Impax obtained final approval of its generic products from the FDA. Likewise, Impax knew that it could make as much or more money by agreeing not to compete with Endo than by actually launching its generic Opana ER product. Had Impax launched generic versions of Opana ER upon receiving FDA final approval for its 5, 10, 20, and 40 mg strengths on June 14, 2010 (representing the vast majority of Opana ER sales) or at the conclusion of the trial, as it was preparing and poised to do prior to the Exclusion Payment Agreement, Impax's generics would have rapidly driven down the price of extended release oxymorphone hydrochloride tablets. Impax was further aware that once its 180 day exclusivity period ran and there were multiple generic versions of Opana ER available, the generics would become a commodity, with little or nothing to distinguish one generic from another except price. Price competition between generics is responsible for much of the dramatic price drop that accompanies generic entry. Impax was well aware of these market dynamics, and knew that it could likely make as much or even more money by agreeing to withhold its generic products in favor of, in effect, splitting Endo's monopoly profits from Opana ER, and that is precisely what happened.

136. With the bench trial underway, Endo and Impax settled the Impax Patent Litigation by contemporaneously entering into the Impax Settlement Agreement and the Impax Development Agreement (together the "Exclusion Payment Agreement") on or about June 8, 2010. The bench trial transcripts were sealed, and on June 15, 2010 the Impax Patent Litigation

was dismissed with prejudice.

2. Impax agrees to delay launching generic Opana ER for two and a half years in exchange for a future cash payment of $102 million and other consideration from Endo

137. In exchange for a future cash payment of $102 million as well as other consideration from Endo, Impax agreed to delay the launch of its generic Opana ER products from June 14, 2010 to January 1, 2013, and to refrain from challenging the validity or enforceability of the ’933 and ’456 patents as well as the ’250 patent, which Endo did not even accuse Impax of infringing. Pursuant to the Exclusion Payment Agreement, Endo granted Impax a license and covenant not to sue for infringement of the ’250, ’933, and ’456 patents as well as any continuations of those patents and to any pending patent applications relating to Opana ER.

138. As a quid pro quo for Impax’s agreement to delay the entry of generic Opana ER and refrain from challenging Endo’s patents, Endo compensated Impax handsomely. In addition to Endo’s grant of a license to Impax for the Penwest time release patents that Impax asserted it was not infringing, the Exclusion Payment Agreement provided several vehicles to provide large and unexplained payments to compensate Impax for its agreement to delay launching its generic.

139. First, the Exclusion Payment Agreement provided for a future cash payment from Endo to Impax if sales of Opana ER fell below a predetermined contractual threshold in the quarter immediately prior to January 1, 2013 (which cash payment in the amount of $102,049,000 was received by Impax in April 2013), an amount far above any litigation costs saved by Endo (or Impax) by settling).

140. Second, the Exclusion Payment Agreement provided that Endo would withhold launch of an authorized generic (“AG”) during Impax’s 180 day exclusivity period, which at the time of the agreement would have been worth many millions of dollars to Impax, well above any litigation costs saved by Endo (or Impax) by settling. Endo’s agreement not to launch an AG

meant that Impax would be the sole generic on the market for at least 180 days, and Impax could therefore obtain all generic sales at higher, supracompetitive prices, all at the expense of Plaintiff and the members of the Class. Endo agreed to forego its own potential profits from the launch of an AG. Absent the unlawful Exclusion Payment Agreement, it would have made economic sense for Endo to launch an AG during Impax's 180 day exclusive marketing period so that Endo could retain some of the sales that Impax's less expensive generic otherwise would capture. Endo would have expected its AG to capture approximately 50% of the generic sales during the first 180 days of generic marketing.

141. Third, the payment included a development and co-promotion agreement whereby Endo paid Impax $10 million up front with an obligation to pay an additional $30 million, ostensibly for certain rights related to Impax's as yet unapproved next generation Parkinson's disease product.

142. To date, pursuant to the Exclusion Payment Agreement, Impax has received at least $112,049,000 in cash (a deferred payment of $102,049,000 explicitly compensating Impax for delaying entry plus an additional $10 million in cash up front as part of the purported Parkinson's drug agreement), and a "no-AG" agreement with a cash value to Impax of millions of dollars in exchange for keeping Impax's generic Opana ER off the market for two and a half years.

143. Defendants have no procompetitive explanation or justification for the payments. This large, unjustified reverse payment had no rational connection to, and far exceeds, any approximation of the costs of continuing the patent litigation that was in the middle of trial at the time the agreement was signed. Nor was the payment consideration for the fair value of any procompetitive services provided by Impax to Endo. In fact, Impax was not required to perform

any service at all (except for delaying entry) in exchange for the more than $102 million cash payment. Impax was also not required to perform any service for the $10 million upfront cash payment that was purportedly related to Impax's unapproved drug product. Endo simply paid Impax not to compete.

144. Absent Endo's unlawful payments to Impax under the Exclusion Payment Agreement, Endo and Impax would have settled in a manner less restrictive of competition, resulting in much less delay of Impax's generic entry than as happened pursuant to a settlement with unlawful payments. Under such an agreement, or even without one (such as with an at-risk launch by Impax, or after a ruling in Impax's favor), Impax would have launched its generic Opana ER substantially earlier than 2013.

145. The likely reason that the future cash payment (the $102 million cash payment from Endo to Impax) called for by the Exclusion Payment Agreement was linked to the sales of Opana ER in the quarter immediately prior to Impax's launch was that Impax was concerned that Endo would switch the market in the interim.

146. In other words, Impax feared that, while it stayed out of the market for two and a half years, Endo would use this period to prepare to switch prescriptions and sales from branded Opana ER to some other brand formulation that Impax's generic would not be AB-rated to (and so not automatically substitutable for). If Endo implemented such a switch before Impax launched its generic, Impax's ability to sell its generic would be greatly impaired, and Impax would make significantly fewer sales than it would have made if it entered after final approval in June 2010 as it had planned because Impax's generic Opana ER would not be AB-rated to the new brand formulation. Hence, in the Exclusion Payment Agreement, Impax made sure that the large reverse payment to Impax was triggered by brand Opana ER sales falling below a certain

threshold in the quarter immediately before the delayed launch date (January 2013) that Impax had agreed to in the Exclusion Payment Agreement. In short, Impax made sure that it would be well paid for staying off the market no matter what happened during the two and a half years of delay.

147. And, if Endo did not successfully switch the market to a new formulation (or did not try), then the monetary value of Endo's promise not to compete with an AG would be much greater, as the sales of brand Opana ER would have remained stable or grown while Impax agreed not to enter the market, and without competition from Endo's AG, Impax could expect to sell its generic at supracompetitive prices and obtain roughly twice as much revenue from selling its generic during its first 180 days than it would otherwise had it faced AG competition.

148. On June 14, 2010, just days after the parties entered into the Exclusion Payment Agreement, Impax received final approval for 5, 10, 20, and 40 mg strengths of generic Opana ER (representing the vast majority of Opana ER sales). On July 22, 2010 Impax received final approval for its 30 mg strength. But, because of the Exclusion Payment Agreement, Impax did not launch until two and a half years later in January 2013.

149. And, indeed, Endo ultimately did undertake efforts to switch the market from Opana ER to a new formulation of Opana ER called Opana ER CRF that was purportedly crush resistant. As a result, Impax received a reverse payment of more than $102 million, and purchasers were left holding the bag.

3. Effects of the Exclusion Payment Agreement

150. The Exclusion Payment Agreement enabled Endo and Impax to (a) delay entry of less expensive generic versions of Opana ER 5, 10, 20, 30, and 40 mg strengths in the United States, (b) fix, raise, maintain or stabilize the price of 5, 10, 20, 30, and 40 mg strengths of Opana ER products, and its generic equivalents, (c) permit Endo to maintain a monopoly in the

United States market for Opana ER and its generic equivalents, and (d) allocate the market for Opana ER and its generic equivalents almost exclusively to Endo through January 2013.

151. The Exclusion Payment Agreement had the effect of delaying competition for 5, 10, 20, 30, and 40 mg oxymorphone hydrochloride extended release tablets for two and a half years. But for this reverse payment agreement, Impax would have begun marketing and selling its generic Opana ER as early as June 14, 2010 for the 5, 10, 20, and 40 mg strengths, and July 22, 2010 for the 30 mg strength, which is when Impax obtained final FDA approval of these strengths of generic Opana ER. Further, but for the no AG provision in the Exclusion Payment Agreement, when Impax did come on the market, Endo would have launched an AG to compete with Impax's generic Opana ER product, pushing generic prices lower.

152. Instead, as a result of the Exclusion Payment Agreement, Impax did not launch its 5, 10, 20, 30, and 40 mg of generic Opana ER tablets until January 4, 2013. Further, pursuant to the terms of the Exclusion Payment Agreement, Endo did not launch a competing AG during Impax's 180 day exclusivity period (thus, Impax got paid cash and through the "no AG" agreement to withhold its generic for two and a half years).

153. In addition, Endo and Impax, the first generic filer for the 5, 10, 20, 30, and 40 mg strengths of generic Opana ER tablets, also knew and intended that their Exclusion Payment Agreement would prevent other generic companies from launching their own generic products in those strengths.

154. As the first-filer of an ANDA with a Paragraph IV certification for generic Opana ER for 5, 10, 20, 30, and 40 mg strengths, Impax was entitled to market its generic Opana ER in those strengths for 180 days free from competition from other generic Opana ER tablets (other than an AG) at those strengths. The operation of the Exclusion Payment Agreement between

Endo and Impax blocked any non-AG generic Opana ER tablets from coming to market until 180 days after January 4, 2013, for those strengths because the FDA will not approve subsequently-filed ANDAs until the first filer's exclusivity period has run. Endo admitted this in its Annual Report: "We expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of generic non-tamper resistant Opana ER commencing on July 1, 2013 [i.e., 180 days after the Impax launch]."

155. In other words, Impax served as a "cork in the bottle." So long as there was not a court ruling invalidating the '456 and '933 patents (which would trigger Impax's 180 day exclusivity period) the delayed launch of the Impax generic called for under the Exclusion Payment Agreement prevented any generic other than Impax, from entering the market until July 2013.

156. Thus, Defendants' Exclusion Payment Agreement delayed or prevented the sale of generic Opana ER 5, 10, 20, 30, and 40 mg strengths in the United States for more than two and a half years, and unlawfully enabled Endo to sell branded Opana ER 5, 10, 20, 30, and 40 mg strengths at artificially inflated, supracompetitive prices.

157. But for Defendants' illegal Exclusion Payment Agreement, generic competition to Opana ER 5, 10, 20, 30, and 40 mg strengths would have occurred as early as June 14, 2010, when Impax received final approval for its ANDA in the 5, 10, 20, and 40 mg dosage strengths and July 22, 2010 for the 30 mg dosage strength. Further, if Impax had launched in June 2010, the market for Opana ER would not have been substantially eroded by the switch to Opana ER CRF, and Impax would have made far more sales. Moreover, the Exclusion Payment Agreement blocked one or more generic manufacturers from launching generic versions Opana ER around December 2010, when Impax's 180-day exclusivity would have expired absent the Agreement.

C. Endo Settles the Actavis, Barr, Sandoz, Watson, and Roxane Patent Litigations

1. Endo settles with Actavis

158. Less than a year after suing Actavis, on or about February 20, 2009, Endo settled all of the Actavis Patent Litigation (the "Actavis Settlement"). On February 25, 2009, the Actavis Patent Litigation was dismissed with prejudice.

159. As discussed above, Actavis was the first-filer on the 7.5 and 15 mg strengths of Opana ER, which are primarily used to taper users on or off of Opana ER. At all relevant times, these two strengths have never constituted more than 10 percent of Endo's Opana ER sales.

160. Under the terms of the Actavis Settlement, Actavis agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Actavis a license permitting the production and sale of generic Opana ER 7.5 and 15 mg tablets by the earlier of July 15, 2011, or the date on which any third party commences commercial sales of a generic oxymorphone hydrochloride extended-release tablets, but not before November 28, 2010. Endo also granted Actavis a license to produce and market other strengths of generic Opana ER generic on the earlier of July 15, 2011 or the date on which any third party commences commercial sales of a generic form of the drug. Endo's subsequent Exclusion Payment Agreement with Impax rendered that portion of the agreement with Actavis illusory as Endo and Impax used Impax's first-filer status to prevent any other generics from launching those strengths earlier than July 2013 (180 days after Impax's January 2013 launch).

161. But for the Exclusion Payment Agreement between Endo and Impax, Actavis would have been able to launch its generic versions of the 5, 10, 20 30, and 40 mg strengths of Opana ER 180 days following Impax's launch of those strengths in June 2010 (and July for the 30 mg). However, due to the Exclusion Payment Agreement, Actavis did not launch those

strengths until mid-2013.[18]

2. Endo settles the Barr, Sandoz, Watson, and Roxane patent litigations

162. On or about April 12, 2010, Endo settled all of the Barr Patent Litigation relating to Opana ER. Under the terms of the settlement, Barr agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Barr a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date became illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Barr could not launch its generic until 180 days after Impax launched in January 2013.

163. The Sandoz litigation had proceeded to a bench trial that was begun on June 3, 2010 before the Honorable Katherine S. Hayden of the United States District Court for the District of New Jersey. On or about June 8, 2010 (the same time as the Endo/Impax Exclusion Payment Agreement and prior to Judge Hayden issuing any dispositive rulings in the bench trial), Endo settled all of the Sandoz Patent Litigation relating to Opana ER. Under the terms of the settlement, Sandoz agreed not to challenge the validity or enforceability of the Opana ER Patents and Endo agreed to grant Sandoz a license permitting the production and sale of the '250, '456, and '933 patents and Endo agreed to grant Sandoz a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Sandoz could not launch its generic until 180 days after Impax launched in January 2013.

[18] Additionally, in March 2011, just before Actavis was able to launch the 7.5 and 15 mg strengths of Opana ER under the terms of the Actavis Agreement, Endo discontinued selling those strengths, impeding Actavis's entry and greatly reducing the sales Actavis otherwise would have made upon launching the first generic versions of the 7.5 and 15 mg strengths.

164. On or about October 4, 2010, Endo settled all of the Watson Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Watson a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Watson could not launch its generic until 180 days after Impax launched in January 2013.

165. On or about May 4, 2011, Endo settled all of the Roxane Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Roxane a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Roxane could not launch its generic until 180 days after Impax launched in January 2013.

166. Notwithstanding agreements for nominal entry dates in 2012, Barr, Sandoz, Watson, and Roxane were not able to sell a generic Opana ER product until 180 days after Impax's generic launch. As such, the real launch date for Barr, Sandoz, Watson, and Roxane generics could not be before July 2013, a delay that Endo secured through Endo's Exclusion Payment Agreement with Impax.

167. The importance of the Barr, Sandoz, Watson, and Roxane settlements for Endo was that they prevented a court ruling that could threaten the validity of the '456 and 933' patents and move up the trigger date for Impax's 180 day exclusivity and the launch of generic Opana ER.

D. As a Result of the Delay Endo Bought with the Illegal Exclusion Payment Agreement with Impax, Endo was Able to Switch the Market from Opana ER to Opana ER CRF, Greatly Reducing the Sales Available to the Generic for Opana ER When it Eventually Entered the Market

168. Endo knew that in 2013 when generics for Opana ER were finally able to come onto the market there would be "substantial share erosion" for brand Opana ER and thus Endo had set about "working on multiple levels to combat that."

169. Accordingly, shortly after buying off Impax and illegally securing an additional two and a half years of its Opana ER monopoly, Endo set about switching the market from Opana ER to Opana ER CRF because generic Opana ER would not be automatically substitutable for Opana ER CRF.

170. The FDA approved Endo's sNDA for Opana ER CRF on December 9, 2011. In approving Opana ER CRF, the FDA did not address any potential competitive effects associated with the approval of the purportedly new formulation or Endo's efforts to move the market from Opana ER to Opana ER CRF. To accomplish the switch between Opana ER and Opana ER CRF, Endo discontinued the sale of Opana ER, requiring physicians desiring to prescribe extended release oxymorphone hydrochloride to prescribe Opana ER CRF instead. Despite Endo's claims to the contrary, the FDA found that Opana ER CRF is not safer than Opana ER and may in fact be more dangerous than Opana ER. Thus, if generic Opana ER would have launched before Opana ER CRF (as would have occurred but for the Exclusion Payment Agreement), the generic would have quickly captured the bulk of brand Opana ER sales, and the subsequent launch of Opana ER CRF (even assuming it still would have launched) would have had little effect on the sales of generic Opana ER.

171. But for the illegal Exclusion Payment Agreement, Endo's launch of Opana ER CRF would have occurred (if it occurred at all) long after generics had entered the market in or

shortly after June 2010 and captured the vast majority of the United States extended release oxymorphone hydrochloride market. As a result, most, if not all, of the prescriptions that are now being filled with Opana ER CRF instead would have been filled with generic extended release oxymorphone hydrochloride.

172. Thus, due to the Exclusion Payment Agreement and the effects flowing from the delayed entry of Impax, Barr, Sandoz, Watson, and Roxane, Plaintiff and the Class continue to suffer overcharges even to this very day.

VI. CLASS ALLEGATIONS

173. Plaintiff brings this action as a class action, under FED. R. CIV. P. 23(a) and (b)(3), on behalf of itself and the following similarly situated End-Payors:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Opana ER 5, 10, 20, 30 and 40 mg tablets and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries (the "Class"), from June 14, 2010 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease (the "the "Class Period").

174. The following persons and entities are excluded from each of the above-described proposed Classes:

i. Defendants and their officers, directors, employees, parent corporations, subsidiaries, affiliates, representatives and/or agents;

ii. All federal or state governmental entities, except cities, towns or municipalities with self-funded prescription drug plans;

iii. All persons or entities that purchased Opana ER or the AB-rated generic equivalent for purposes of resale and/or directly from Defendants or their affiliates;

iv. Fully insured health care plans (i.e., health care plans that purchased insurance from a third-party payer covering 100% of a plan's reimbursement obligations to its members);

v. Any "flat co-pay" consumers whose purchases were paid, in part, by a third-party payor, and whose co-payment was the same regardless of the retail purchase price;

vi. Pharmacy Benefit Managers without capitation agreements;

vii. All Counsel of Record; and

viii. The Court, Court personnel and any members of their immediate families.

175. Members of the Class are so numerous that joinder is impracticable. On information and belief, the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

176. Plaintiff's claims are typical of those of each of the Class members. Plaintiff and Class members were damaged by the same wrongful conduct of Defendants, i.e., as a direct and proximate result of Defendants' wrongful conduct, they paid artificially inflated prices for Opana ER 5, 10, 20, 30, and 40 mg and were deprived of the benefits of earlier and robust competition from cheaper generic versions of the products.

177. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the Class members.

178. Plaintiff is represented by counsel with experience in prosecuting class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

179. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class, and Defendants' unlawful conduct has inflicted antitrust injury in the form of overcharges to the Class. Such generally applicable conduct is

inherent in Defendants' wrongful conduct.

180. Questions of law and fact common to the Class include:

a. whether Defendants conspired to restrain generic competition to Opana ER;

b. whether Impax unlawfully agreed to delay its entry into the market for extended release oxymorphone hydrochloride tablets, i.e., Opana ER and its AB-rated generic bioequivalents;

c. whether Endo paid Impax in exchange for a delay in generic competition for Opana ER;

d. whether Endo's compensation to Impax was necessary to yield some procompetitive benefit that is legally cognizable and non-pretextual;

e. whether Defendants' challenged conduct suppressed generic competition to Opana ER;

f. whether Defendants' challenged conduct harmed competition in the market for extended release oxymorphone hydrochloride, i.e., Opana ER and its AB-rated generic bioequivalents;

g. whether Endo possessed market power in the market for extended release oxymorphone hydrochloride, i.e., Opana ER and its AB-rated generic bioequivalents;

h. whether the relevant antitrust market (if a relevant market must be defined) is the market for extended release oxymorphone hydrochloride, i.e., Opana ER and its AB-rated generic bioequivalents;

i. whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;

j. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and

k. the quantum of overcharges paid by Plaintiff and the Class in the aggregate.

181. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated,

geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

182. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. INTERSTATE AND INTRASTATE COMMERCE

183. Defendants' anticompetitive conduct has affected interstate and intrastate commerce.

184. At all relevant times, Endo manufactured, promoted, distributed, and sold substantial amounts of Opana ER in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

185. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Opana ER and its generic equivalent.

186. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

187. Defendants' anticompetitive conduct also had substantial intrastate effects in that,

inter alia, retailers within each state were foreclosed from offering cheaper generic Opana ER to End-Payors inside each respective state. The complete foreclosure of generic Opana ER directly impacted and disrupted commerce for End-Payors within each state (and will continue to do so).

188. During the relevant time period, Opana ER, and its generic equivalent were shipped into each state and were sold to or paid for by End-Payors in each state. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in each state because Opana ER, and its generic equivalent were sold to End-Payors in each state at supracompetitive prices and Defendants entered into unlawful anticompetitive agreements that affected commerce in each state.

VIII. MARKET POWER AND RELEVANT MARKET

189. At all relevant times, Endo had market power over extended release oxymorphone hydrochloride – including Opana ER and its AB-rated generic equivalents – because Endo had the power to maintain the price of extended release oxymorphone hydrochloride at supracompetitive levels without losing substantial sales to other daily pain management products. This market power may be shown directly, and therefore no relevant market needs to be defined.

190. A small but significant, non-transitory price increase for Opana ER by Endo would not have caused a significant loss of sales to other pain medications sufficient to make such a price increase unprofitable.

191. Opana ER does not exhibit significant, positive cross-elasticity of demand with respect to price, with any other daily pain management product other than AB-rated generic versions of Opana ER.

192. Opana ER is not reasonably interchangeable with any products other than AB-

rated generic versions of Opana ER.

193. The existence of non-Opana ER pain medications did not constrain Endo's ability to raise or maintain Opana ER prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market with Opana ER. Therapeutic alternatives are not the same as economic alternatives.

194. Functional similarities between Opana ER and non-Opana ER pain medication products are insufficient to permit inclusion of those other pain medication products in the relevant market with Opana ER. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other pain medication (except for AB-rated generic versions of Opana ER) will take away sufficient sales from Opana ER to prevent Endo from raising or maintaining the price of Opana ER above levels that would prevail in a competitive market.

195. Opana ER is also not reasonably interchangeable with any products other than AB-rated generic versions of Opana ER because Opana ER has different attributes significantly differentiating it from other pain medications and making it unique. The FDA does not consider Opana ER and other pain medications interchangeable.

196. Price does not drive prescriptions for pain medications. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Opana ER, to patients without a prescription written by a doctor. This prohibition introduces a disconnect between the payment obligation and the product selection. The patient

(and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

197. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

198. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs, such as pain management products, is made by the physician, not by consumers of those products. Consequently, despite the existence of a number of different pain management products a physician could have started a patient on, or in theory could switch a patient to, once the physician and patient find one that is well-tolerated, it is unlikely that the patient will switch to a different pain management product based on variations of price.

199. Doctors generally select a pain medication for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price. For clinical reasons, among others, physicians and patients prefer Opana ER to other pain medications.

200. The existence of other products designed to manage pain has not significantly constrained Endo's pricing of Opana ER.

201. Endo needed to control only Opana ER and its AB-rated generic equivalents, and no other products, in order to maintain the price of Opana ER profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Opana ER would

render Endo unable to profitably maintain its current prices of Opana ER without losing substantial sales.

202. The entry of other brand pain medications (or generic versions of those other brands) did not take substantial sales from Opana ER or cause Endo to lower its price. By contrast, the competitive impact of an AB-rated generic version of Opana ER on brand Opana ER would be substantial. Among other things, the entry of an AB-rated generic Opana ER would deliver hundreds of millions of dollars of savings to purchasers.

203. At all relevant times, Endo has sold Opana ER at prices well in excess of the competitive price.

204. At all relevant times, Endo had, and exercised, the power to exclude and restrict competition to Opana ER and AB-rated bioequivalents.

205. At all relevant times, Endo enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

206. To the extent that Plaintiff is legally required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is extended release oxymorphone hydrochloride tablets (i.e., Opana ER and its AB-rated generic equivalents). During the relevant time, Endo has been able to profitably maintain the price of extended release oxymorphone hydrochloride tablets well above competitive levels.

207. The relevant geographic market is the United States and its territories.

208. Endo's market share in the relevant market was either 100% or close to 100% at all relevant times.

IX. MARKET EFFECTS AND DAMAGES TO THE CLASS

209. But for the anticompetitive conduct alleged above, Impax would have entered the market with its generic Opana ER as early as June 14, 2010 when it received final FDA approval for the 5, 10, 20, and 40 mg oxymorphone hydrochloride extended release strengths, and July 22, 2010 when Impax received final FDA approval for the 30 mg strength. Other generic manufacturers would have entered the market with additional generic versions of Opana ER thereafter.

210. But for the anticompetitive conduct alleged above, Endo's efforts to switch the market from Opana ER to Opana ER CRF would not have significantly affected Impax's ability to make sales of its generic version of Opana ER because absent the delay paid for by Endo, Impax would have launched well before Endo launched Opana ER CRF, and the vast bulk (on the order of 90%) of the sales of Opana ER would have been switched to Impax's generic product before the launch of Opana ER CRF (assuming it would have launched at all).

211. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Opana ER from generic competition.

212. Impax, Actavis, Barr, Roxane, and Watson have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

213. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of 5, 10, 20, 30, and 40 mg Opana ER, has caused Plaintiff and the Class to pay more than they would have paid for extended release oxymorphone

hydrochloride tablets absent Defendants' illegal conduct.

214. Typically, generic drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, virtually all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug.

215. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

216. But for Defendants' anticompetitive conduct, Plaintiff and members of the Class would have paid less for extended release oxymorphone hydrochloride tablets by: (a) substituting purchases of less-expensive AB-rated generic Opana ER for their purchases of more-expensive branded Opana ER; (b) paying reduced prices on their remaining brand Opana ER purchases; and (c) purchasing generic Opana ER at lower prices sooner.

217. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) launching generic versions of Opana ER, and/or (b) challenging the validity or infringement of the '456, '933, and '250 patents (i.e., the Penwest time release patents) in court.

218. At all relevant times during the Class Period, Plaintiff and the Class members indirectly purchased substantial amounts of Opana ER. As a direct and proximate result of

Defendants' illegal conduct, Plaintiff and the Class members were compelled to pay, and did pay, artificially inflated prices for Opana ER and its generic equivalents. Plaintiff and the Class members paid prices substantially greater than the prices they otherwise would have paid absent Defendants' illegal conduct because Class members: (i) were deprived of the opportunity to purchase lower-priced generic Opana ER instead of expensive brand Opana ER, and (ii) paid artificially inflated prices for Opana ER and its generic equivalents.

219. As a direct and proximate result of Defendants' unlawful anticompetitive scheme and wrongful conduct, Plaintiff and Class members have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for Opana ER and its generic equivalents, the exact amount of which will be proven at trial.

220. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT

221. Overcharges for pharmaceuticals at a higher level of distribution generally result in higher prices at every level below.

222. Wholesalers and retailers passed on the inflated prices of branded Opana ER and AB-rated generic Opana ER to Plaintiff and Class members.

223. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

224. The inflated prices paid by Plaintiff and Class members are traceable to, and the direct, proximate and foreseeable result of, Defendants' overcharges.

225. General economic theory recognizes that any overcharge at a higher level of

distribution in the chain of distribution for Opana ER results in higher prices at every level below. Herbert Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE 624 (1994). Professor Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." *Id.* He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level." *Id.*

226. Defendants' anticompetitive conduct enabled them to charge consumers indirectly and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

227. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

228. The inflated prices Plaintiff and members of the Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade under State Law
(Asserted by Plaintiff and the Class against Endo and Impax)

229. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

230. Endo and Impax entered into the Exclusion Payment Agreement to suppress generic competition for Opana ER. The Exclusion Payment Agreement has involved the conduct set forth above. The Exclusion Payment Agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which to:

a. Allocate close to 100% of the market for Opana ER in the United States to Endo;

b. Prevent the sale of generic versions of Opana ER in the United States, thereby nearly completely protecting Opana ER from generic competition for at least two years and six months during which time Endo could switch the market for Opana ER to Opana ER CRF;

c. fix, raise, maintain or stabilize the price at which End-Payor purchasers would pay for Opana ER or its AB-rated generic equivalent at supracompetitive levels; and

d. allocate close to 100% of United States generic Opana ER sales to Impax during the first 180 days of generic sales.

231. The Exclusion Payment Agreement harmed Plaintiff and the Class as set forth above.

232. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

233. The Exclusion Payment Agreement between Endo and Impax regarding Opana ER involves (i) large and unjustified payments from Endo to Impax ($102 million and other consideration), and (ii) an agreement by Impax to delay marketing its generic Opana ER. The payments from Endo to Impax under the Agreement were the quid pro quo for Impax's agreement to delay marketing its generic versions of Opana ER. Absent the payments, Impax would not have agreed to delay marketing its generic versions of Opana ER and would have entered the market sooner than it did.

234. The purpose and effect of the payments flowing from Endo to Impax under the Exclusion Payment Agreement were to delay generic competition to Opana ER. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the

payments were not necessary to achieve such a purpose.

235. The purpose and effect of the unlawful Exclusion Payment Agreement between Endo and Impax were to allocate 100% of the market for Opana ER and its generic equivalents in the United States to Endo, delay the sale of generic Opana ER products, and fix the price at which consumers and other End-Payors would pay for Opana ER and its generic equivalents at the higher, branded price.

236. The Exclusion Payment Agreement harmed competition.

237. The Exclusion Payment Agreement between Defendants is a horizontal market allocation and price fixing agreement between actual and potential competitors and is an unreasonable restraint of trade, in violation of state antitrust law, under a "rule of reason" analysis.

238. As a direct and proximate result of Endo's and Impax's unlawful restraint of trade, Plaintiff and Class members paid artificially inflated prices for Opana ER and its generic equivalents as described herein, and were harmed as a result.

239. By engaging in the foregoing conduct, Endo and Impax intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

a. Arizona Rev. Stat. §§ 44-102, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Opana ER in California by members of the Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.

e. Hawaii Code § 480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.

g. Iowa Code § 553, *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Opana ER in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Opana ER Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.

m. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class.

o. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Opana ER in New Hampshire by members of the Class.

p. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.

q. New York General Business Law § 340, *et seq.*, with respect to purchases of Opana ER in New York by members of the Class.

r. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of Opana ER in North Carolina by members of the Class.

s. N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Opana ER in Oregon by members of the Class.

u. 10 L.P.R.A. § 258 with respect to purchases of Opana ER in the Commonwealth of Puerto Rico by members of the Class.

v. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.

w. S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class.

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.

z. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.

aa. W.Va. Code §§ 47-18-1, et seq., with respect to purchases of Opana ER in West Virginia by members of the Class.

bb. Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class.

240. Plaintiff and Class members have been (and will continue to be) injured in their business or property by reason of Endo's and Impax's antitrust violations, in that Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Opana ER, and (ii) paid higher prices for branded Opana ER than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

241. Plaintiff and Class members seek damages and multiple damages as permitted by law for their injuries.

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law
(Asserted by Plaintiff and the Class against Endo Defendants)

242. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

243. This claim is pled as to the Endo Defendants.

244. At all relevant times, the Endo Defendants possessed substantial market power (i.e., monopoly power) in the relevant market. The Endo Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

245. Through the anticompetitive conduct, as alleged extensively above, the Endo Defendants willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

246. It was the Endo Defendants' conscious objective to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

247. The Endo Defendants' anticompetitive conduct harmed competition as alleged herein.

248. There is and was no legitimate, non-pretextual, procompetitive justification for the Endo Defendants' actions comprising the anticompetitive conduct that outweighs the scheme's harmful effects. Even if there were some conceivable such justification, the conduct is and was broader than necessary to achieve such a purpose.

249. As a direct and proximate result of the Endo Defendants' illegal and monopolistic conduct, as alleged herein, Plaintiff and Class members were injured.

250. By engaging in the foregoing wrongful conduct, the Endo Defendants intentionally and wrongfully maintained monopoly power over the sale of Opana ER and its generic equivalents, in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of Opana ER in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.

e. Hawaii Code §480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.

g. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.

h. Kansas Stat. Ann § 50-161(b), *et seq.*, with respect to purchases of Opana ER in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of Opana ER in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class.

o. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Opana ER in New Hampshire by members of the Class.

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.

q. N.Y. Gen. Bus. Law §340, *et seq.*, ("The Donnelly Act"), with

respect to purchases of Opana ER in New York by members of the Class.

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Opana ER in North Carolina by members of the Class.

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Opana ER in Oregon by members of the Class.

u. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Opana ER in Puerto Rico by members of the Class.

v. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.

x. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class.

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.

z. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Opana ER in West Virginia by members of the Class.

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class.

251. Plaintiff and Class members have been (and will continue to be) injured in their business or property by reason of the Endo Defendants' antitrust violations, in that Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Opana ER, and (ii) paid higher prices for branded Opana ER than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the

conduct unlawful.

252. Plaintiff and Class members seek damages and multiple damages as permitted by law for their injuries.

THIRD CLAIM FOR RELIEF
Attempted Monopolization under State Law
(Asserted by Plaintiff and the Class against Endo Defendants)

253. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

254. Through the Exclusion Payment Agreement and related conduct, Endo Defendants specifically intended to maintain monopoly power in the relevant market. It was the Endo Defendants' conscious objective to control prices and/or to exclude competition in the relevant market.

255. The natural and probable consequence of Endo Defendants' anticompetitive conduct, which was intended by them, and plainly foreseeable to them, was to control prices and exclude competition in the relevant market.

256. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Endo Defendants would succeed in and achieve their goal of maintaining monopoly power in the relevant market.

257. As a direct and proximate result of the Endo Defendants' illegal and monopolistic conduct, Plaintiff and the Class were harmed as alleged herein.

258. By engaging in the foregoing conduct, the Endo Defendants intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of Opana ER in California by

members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.

e. Hawaii Code §480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.

g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of Opana ER in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class.

n. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Opana ER in New Hampshire by members of the Class.

o. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.

p. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Opana ER in North Carolina by members of the Class.

q. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.

r. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of

Opana ER in Oregon by members of the Class.

s. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Opana ER in Puerto Rico by members of the Class.

t. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.

u. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.

v. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class.

w. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.

x. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.

y. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Opana ER in West Virginia by members of the Class.

z. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class.

259. Plaintiff and Class members have been (and will continue to be) injured in their business or property by reason of the Endo Defendants' antitrust violations, in that Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Opana ER, and (ii) paid higher prices for branded Opana ER than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

260. Plaintiff and Class members seek damages and multiple damages as permitted by law for their injuries.

FOURTH CLAIM FOR RELIEF
State Consumer Protection Violations
(Asserted by Plaintiff and the Class against All Defendants)

261. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

262. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and Class members were deprived of the opportunity to purchase a generic equivalent of Opana ER and forced to pay higher prices for their Opana ER requirements.

263. For years, there was a gross disparity between the price that Plaintiff and the Class members paid for the brand product when compared to the less expensive generic products, which should have been available.

264. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

a. Defendants have engaged in unfair or unconscionable acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, *et seq.*

b. Defendants have engaged in unfair or unconscionable acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*

c. Defendants have engaged in unfair or unconscionable acts or practices or made false representations in violation of D.C. Code §§ 28-3901, *et seq.*

d. Defendants have engaged in unfair or unconscionable acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*

e. Defendants have engaged in unfair or unconscionable acts or practices in violation of Haw. Rev. Stat §§ 480, *et seq.*

f. Defendants have engaged in unfair or unconscionable acts or practices in violation of Idaho Code Ann. §§ 48-601, *et seq.*

g. Defendants have engaged in unfair or unconscionable acts or

practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*

h. Defendants have engaged in unfair or unconscionable acts or practices in violation of Iowa Code section §§ 714.16, *et seq.*

i. Defendants have engaged in unfair or unconscionable acts or practices in violation of Kan. Stat. Ann, §§ 50-623, *et seq.*

j. Defendants have engaged in unfair or unconscionable acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207, *et seq.*

k. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mass. Gen. Laws Ch. 93A, *et seq.*

l. Defendants have engaged in deceptive or fraudulent acts or practices in violation of Minn. Stat. §§ 83l, 325D.44, subd. 1(5), (7) and (13) and 325F.69, subd. 1.

m. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mo. Ann. Stat. §§ 407.010, *et seq.*

n. Defendants have engaged in unfair or unconscionable acts or practices in violation of Neb. Rev. Stat. §§ 59.1601, *et seq.*

o. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:l, *et seq.*

p. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.M. Stat. Ann. §§ 57-12-1, *et seq.*

q. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.* Plaintiff seeks single damages under this statute.

r. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.C. Gen. Stat. §§ 75-l.l, *et seq.*

s. Defendants have engaged in deceptive or fraudulent acts or practices in violation of N.D. Cent. Code §§ 51-15-01, *et seq.*

t. Defendants have engaged in unfair or unconscionable acts or practices in violation of 73 Pa. State. Ann. §§ 201-1, *et seq.*

u. Defendants have engaged in unfair or unconscionable acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*

v. Defendants have engaged in deceptive or fraudulent acts or practices in violation of S.D. Codified Laws §§ 37-24-1, *et seq.*

w. Defendants have engaged in unfair or unconscionable acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2451, *et seq.*

x. Defendants have engaged in unfair or unconscionable acts or practices in violation of W. Va. Code §§ 46A-6-101 *et seq.*

265. Plaintiff and the Class have been injured in their business and property by reason of Defendants' unfair or unconscionable acts or practices alleged herein. Their injury consists of paying higher prices for Opana ER than they would have paid in the absence of such violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Regarding Opana ER
(Asserted by Plaintiff and the Class against All Defendants)

266. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

267. Defendants have benefited from splitting the supracompetitive profits on Endo's Opana ER sales resulting from the unlawful and inequitable acts alleged herein.

268. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Opana ER by Plaintiff and Class members.

269. Plaintiff and Class members have conferred upon Defendants an economic benefit in the nature of profits resulting from unlawful overcharges and supracompetitive profits – to the economic detriment of Plaintiff and Class members.

270. It would be futile for Plaintiff and Class members to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiff and Class members.

271. It also would be futile for Plaintiff and Class members to exhaust any remedy they might have against any immediate intermediary in the chain of distribution from which they indirectly purchased Opana ER. Any such intermediaries are not liable and would not

compensate Plaintiff and Class members for harm caused by Defendants.

272. The economic benefit in the form of overcharges and unlawful profits derived by Defendants through charging supracompetitive and artificially inflated prices for Opana ER is a direct and proximate result of Defendants' unlawful practices.

273. The financial benefits derived by Defendants rightfully belong to Plaintiff and Class members because they paid anticompetitive and supracompetitive prices during the Class Period that wrongfully inured to the benefit of Defendants.

274. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendants to retain any of the overcharges for Opana ER derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged herein.

275. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and Class members all unlawful or inequitable proceeds received by them.

276. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and Class members.

277. Plaintiff and Class members have no adequate remedy at law.

SIXTH CLAIM FOR RELIEF
For Declaratory and Injunctive Relief under Section 16 of the Clayton Act for Defendants' Violations of Sections 1 and 2 of the Sherman Act (Against All Defendants)

278. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

279. Plaintiff's allegations described herein and in the preceding Counts comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state laws supra.

280. Plaintiff and the End-Payor Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §

2201(a), hereby seek a declaratory judgment that Defendants' conduct, in seeking to prevent competition as described herein, violates Sections 1 and 2 of the Sherman Act.

281. Plaintiff and the End-Payor Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, individually and on behalf of the Class, respectfully demands judgment for the following relief:

A. Certification of this action as a class action, pursuant to Fed. R. Civ. P. 23(a), 23 (b)(2) and (b)(3), direction of reasonable Class notice, pursuant to by Fed. R. Civ. P. 23(c)(2), appointment of Plaintiff as representative of the Class, and appointment of Plaintiff's counsel as Class Counsel;

B. A finding that Defendants' wrongful conduct alleged herein violated the statutes set forth above, and constitutes unjust enrichment under the common law of all states and jurisdictions within the United States, except Indiana and Ohio;

C. Joint and several judgments against Defendants in favor of Plaintiff and the Class;

D. Equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

E. Plaintiff's and Class members' damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

F. Attorneys' fees, litigation expenses, and costs of suit; and

G. Such other and further relief as necessary to correct the anticompetitive market effects caused by Defendants' unlawful conduct, and as the Court deems just.

XIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: June 19, 2014

Respectfully submitted,

/s/ Kenneth A. Wexler

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